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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,056	10/24/2003	Joost A. Kolkman	022013-000160US	1550

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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,056	KOLKMAN ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95-107* is/are pending in the application.

4a) Of the above claim(s) *99,102,104 and 105* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95-98,100,101,103,106 and 107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/9/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice of Non-Compliant Amdt*.

Continuation of 4(e) Other: Withdrawn claims were not identified with proper status identifiers.

DETAILED ACTION

Claim Status

1. Claims 1-94 have been cancelled filed on 4/17/06.

Claims 95-107 are currently pending.

Claims 99, 102, 104 and 105 have been withdrawn.

Claims 95-98, 100, 101, 103, 106 and 107 are being examined in this application.

Non-Compliant Claim Amendment

2. Applicants have amended the claims, however, the claim amendment is not compliant. Applicants are respectively directed to the attached "Notice of Non-compliant Amendment" for additional information.

Election/Restrictions

3. Applicants elected the following species:

(A) the following number of monomer domains: two

(B) the following specific sequence for the first monomer domain: CPANEFQCRNSSTCIPRRWLCDGDDDCGDGSDETGCSAPASEPPGSL;

(C) the following specific sequence for the second monomer domain: CQPDQFRCSSGRCLSREWLCDGEDDCEDDSDETDCPTRTSLQ;

(F) the following cells: bacterial cells;

(G) the following first target molecule: IgE;

(H) the following second target molecule: IgE;

in the Reply filed on 10/16/06 is as previously acknowledged.

Priority

4. This application is a CIP of 10/289,660 (filed on 11/06/2002; now ABN), which is a CIP of 10/133,128 (filed 04/26/2002), which claims benefit of the following provisional applications:

60/374,107 04/18/2002;

60/333,359 11/26/2001;

60/337,209 11/19/2001;

60/286,823 04/26/2001.

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/286,823, filed on 4/26/01, fails to provide adequate support or enablement in the manner provided by the first

paragraph of 35 U.S.C. 112 for one or more claims of this application. For examples, the '823 provisional patent does not provide support for LDL-receptor Class A domain and the consensus sequence such as the one depicted by SEQ ID NO:331. The current application obtains the priority date of 60/337,209.

Thus, the effective filing date of the instant application is 11/19/01.

Information Disclosure Statement

6. The IDS filed on 4/9/07 has been considered. See the attached PTO 1449 forms.

Oath/Declaration

7. The newly submitted ADS (5/7/07) to include the Inventor, Per-Ola Freskgard's information is acknowledged.

Claim Objection(s) / Rejection(s) Withdrawn

8. In light of applicants' amendments to the claims and supporting arguments, the objection against Claim 106 in the previous office action is withdrawn.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 95-98, 100, 101, 103, 106 and 107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

11. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue the claim language (Claim 95) is not indefinite. Applicants state "To properly construe a claim, all the limitations of the claims must be considered and given weight (MPEP §2143.03)". Applicants also state "the 'conflicting' limitations alleged by the Examiner operate together to define the scope of the claimed invention". (Reply, p. 7)

However, applicants further state that the limitation of "non-naturally-occurring amino acid sequence" is "separate" from the limitation relating to "SEQ ID NO:331". (Reply, p. 7).

As stated previously, the instant specification does not explicitly define the term "non-naturally-occurring amino acid sequences". When the specification does not explicitly define a given term, the term should be given its broadest reasonable interpretation.

"The ordinary and customary meaning of a term may be evidenced by a variety of sources, >including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning

of technical terms, and the state of the art."< Phillips v. AWH Corp., *>415 F.3d at 1314<, 75 USPQ2d **>at 1327." (MPEP 2111.01 III).

As discussed previously, the term "non-naturally occurring amino acid sequences" can be construed variously to encompass different amino acid sequences. A so-called "wild-type" sequence known in the art may or may not fall within the scope of "non-naturally occurring sequences". SEQ ID NO:331 encompasses a variety of sequences that include wild-type sequences. Thus, if one of ordinary skill in the art rely on the various sequences depicted in SEQ ID No:331 to define the term "non-naturally occurring amino acid sequences", one would include the so-called "wildtype" sequences for the "non-naturally occurring amino acid sequences".

In addition, it is also unclear what portion of the sequence should be "non-naturally occurring". For examples, sequences with partial wild-type sequence would also read on the instant claims.

Thus, it is not clear what the term "non-naturally occurring amino acid sequences" encompasses, and what sequence(s) are excluded by the said term.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Esser

13. Claims 95, 100, 103, 106 and 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Esser et al (Journal of Biological Chemistry. Vol. 263: 13282-13290; 1988). This rejection is necessitated by applicants' amendments to the claims. The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

14. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue the cited reference does not teach all claimed elements of "two LDL-receptor class A monomer domains". Specifically, the reference does not teach "each" of the monomer domains having "non-naturally-occurring sequences". (Reply, p. 9, para 1).

As discussed above, the term "non-naturally-occurring sequences" are not explicitly defined in the instant specification. It is not clear what sequences are excluded or included from the said term. The dictionary defines the term "non-natural" as "not produced by or involving natural processes" (Definition for "non-natural" from Compact Oxford English Dictionary; downloaded from http://www.askoxford.com/concise_oed/nonnatural?view=uk; downloaded on 7/18/07), which does not conflict with the usage of the said term in the instant disclosure.

The instant claims recite a consensus sequences (i.e. SEQ ID NO:331) as the claimed monomer domain sequences. As discussed in the previous office action (mailed 11/06/06; pp. 6-8), each of the different "repeats" of the Esser reference matches the consensus sequence of SEQ

ID NO:331. Because the polypeptides comprising these repeats (or monomer domains) are not "produced by natural process", the "repeats" within the polypeptides described in the Esser reference are "non-naturally occurring".

Applicant's argument regarding the number of amino acid mutations within each "repeat" is irrelevant, because the instant claims do not limit the number or the type of mutations the monomer domains need to possess. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., mutations in at least two repeats (or monomer domains)) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The "repeats" or (monomer domains) taught by Esser matches the sequences recited in SEQ ID NO:331, and are not made by natural processes. Thus, the reference teach each and every elements of the claimed invention.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Esser, Bajari, Russell and Rudolph

16. Claims 95-98, 100, 101, 103, 106 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esser et al (Journal of Biological Chemistry. Vol. 263: 13282-13290; 1988), in view of Bajari et al (Biological Chemistry. Vol. 379: 1053-1062; Aug/Sept., 1998), and if necessary further in view of Russell et al (Journal of Biological Chemistry. Vol. 264 (36): 21682-21688; 1989), and Rudolph et al (The FASEB Journal. Vol. 10: p. 49-56; 1996). The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

17. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants argue that the above cited reference do not teach all elements of the claimed invention. (Reply, pp. 9-11).

Applicants made the above assertion by attacking each of the cited reference individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants are respectively directed to the discussion under the Esser reference for answer to argument regarding the teaching of the Esser reference.

Applicants also seem to argue that none of the cited reference teaches "mutations" in at least two "Repeats" (or monomer domains). (Reply, pp. 11-12).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., mutations in at least two repeats (or monomer domains)) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants also assert "the Examiner has not articulated any reasoning or rationale to combine any of the teachings of Bajari, et al., Russell, et al., or Rudolph, et al., with Esser, et al., to arrive at the claimed invention, or to support the Examiner's conclusion of obviousness". (Reply, p. 13, para 3).

Contrary to applicant's assertion, the previous Office action (mailed 11/06/06) provides clear reasoning or motivation to combine the cited reference. Applicants are respectively directed to the Office action, mailed 11/06/06, pp. 9-11; especially pp. 10-11 for motivation statements).

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claim 95-98 and 103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 22, 24, 25, and 31 of copending Application No. 10/971,679 (20050164301; filed 10/22/04). The previous rejection is maintained for the reasons of record as set forth in the previous Office action.

Discussion and Answer to Argument

20. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants state that the above ODP rejection should be withdrawn due to allowability of the instant claims.

However, the instant claims are remain rejected, and thus the above ODP rejection is maintained for the reason of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SL
Art Unit 1639
7/18/07

/Jon D. Epperson/
Primary Examiner, AU 1639

Notice of Non-Compliant Amendment (37 CFR 1.121)	Application No.	Applicant(s)	
	10/693,056	KOLKMAN ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 5/7/07 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other _____.
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: *See Continuation Sheet*.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):

_____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.

2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

   Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

   Failure to timely respond to this notice will result in:
   Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
   Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

_____ _____

Legal Instruments Examiner (LIE), if applicable Telephone No.